UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 9, 2021

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-36728	56-2590442
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
465 State Route 17, Ramsey, New Jersey		07446
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: (201) 478-5552

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADMA	Nasdaq Global Market
Preferred Share Purchase Rights	-	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

On December 9, 2021, ADMA Biologics, Inc., a Delaware corporation (the "Company"), announced that the European Patent Office (EPO) has issued European Patent No. 3375789, to the Company. This patent relates to the treatment and prevention of *S. pneumonia* infections, and in particular, to standardized hyperimmune globulins containing elevated antibody titers for a plurality of *S. pneumoniae* serotypes. A copy of the Company's press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release of the Company, dated December 9, 2021
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

December 9, 2021

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz
Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

ADMA Biologics Provides Update on Global Intellectual Property Portfolio

Extends Existing U.S. Patent with Granted European Patent for Treatment and Prevention of S. Pneumococcal Infections with a Hyperimmune Globulin

Reinforces Existing and Pending IP that Provides for 'Spiking' IG Pools with Monoclonal Antibodies to Create Novel Hyperimmune Globulins

RAMSEY, NJ and BOCA RATON, FL – December 9, 2021 – ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA" or the "Company"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics, today announced that the European Patent Office (EPO) has issued European Patent No. 3375789, to the Company. This patent relates to the treatment and prevention of *S. pneumonia* infections, and in particular, to standardized hyperimmune globulins containing elevated antibody titers for a plurality of *S. pneumoniae* serotypes. This EPO granted patent complements ADMA's existing U.S. Pat. Nos. 10,259,865 and 11,084,870.

"This European patent, which augments ADMA's existing U.S. patent estate, highlights the Company's emerging position as a thought leader in the development and commercialization of hyperimmune globulins which, we believe, will attract additional collaborators interested in pursuing these areas of significant unmet medical need," stated Adam Grossman, President and Chief Executive Officer of ADMA. "The EPO's issuance of the *S. pneumonia* patent, together with our previously granted U.S. patents, provides protection for the potential development of a *S. pneumonia* hyperimmune globulin. Despite widespread availability of U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA)-approved vaccines, all-cause pneumonia is among the leading causes globally of vaccine preventable illness and deaths, particularly among vulnerable patient populations, including the immune compromised and the elderly. It is in this patient population that we believe a pneumococcal hyperimmune globulin will find significant medical utility and prove to be a favorable end-market if successfully developed."

Mr. Grossman continued: "ADMA continues to aggressively pursue its proprietary, therapeutic technologies and associated intellectual property (IP). In addition to its marketed and pipeline hyperimmune respiratory syncytial virus (RSV) immune globulin (IG) and hyperimmune S. *pneumonia* IG products, today's announcement underscores ADMA's capabilities to develop, commercialize and protect its tailored IG pools technology, containing for example, one or more antibodies that are added or 'spiked' into an IG pool. We believe this novel, exciting therapeutic approach has the potential to significantly accelerate and expand the development of hyperimmune globulins into a variety of infectious disease categories and therapeutic indications. The Company will continue to explore these and other hyperimmune development opportunities, and we are confident ADMA's unique IP estate will provide significant value and IP breadth to a strategic partner possessing its own commercial product IP."

Regarding the 'spiking' of monoclonal antibodies into IG, this approach was recently referenced during the FDA's Blood Products Advisory Committee (BPAC) meeting on November 4, 2021. Specifically, panelists discussed escape mutants for Hepatitis B virus (HBV) and how current vaccines and antiviral medications may not cover these emerging strains. FDA discussions evolved into the possibility of using IG with monoclonal antibodies to combat and protect from emerging mutant strains, the very same platform ADMA has positioned itself over the past several years to develop, commercialize and protect.

About ADMA Biologics, Inc. (ADMA)

ADMA is an end-to-end American commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for certain infectious diseases. ADMA currently manufactures and markets three FDA-approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases: BIVIGAM® (immune globulin intravenous, human) for the treatment of primary humoral immunodeficiency (PI); ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of PI; and NABI-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against the Hepatitis B virus. ADMA manufactures its immune globulin products at its FDA-licensed plasma fractionation and purification facility located in Boca Raton, Florida. Through its ADMA BioCenters subsidiary, ADMA also operates as an FDA-approved source plasma collector in the U.S., which provides a portion of its blood plasma for the manufacture of its products. ADMA's mission is to manufacture, market and develop specialty plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases and management of immune compromised patient populations who suffer from an underlying immune deficiency, or who may be immune compromised for other medical reasons. ADMA has received U.S. Patents 9,107,906, 9,714,283, 9,815,886, 9,969,793 and 10,259,865 and European Patent No. 3375789 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 about ADMA Biologics, Inc. and its subsidiaries (collectively, "we," "our" or the "Company"). Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain such words as "estimate," "project," "intend," "forecast," "confident," "target," "anticipate," "plan," "potential," "planning," "expect," "believe," "will," "should," "could," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements also include, but are not limited to, statements about ADMA's intellectual property portfolio and its corresponding value. Actual events or results may differ materially from those described in this press release due to a number of important factors. Current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. Except to the extent required by applicable laws or rules, ADMA does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause our actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

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